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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/506,548	09/03/2004	Hisashi Narimatsu	Q83405	8749

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EXAMINER

CHOWDHURY, IQBAL HOSSAIN

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 08/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/506,548	<b>Applicant(s)</b> NARIMATSU ET AL.	
	<b>Examiner</b> Iqbal Chowdhury, Ph.D.	<b>Art Unit</b> 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 24 April 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 9-14 is/are pending in the application.
- 4a) Of the above claim(s) 6, 9-12 and 14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 September 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>9/04</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

This application is a 371 of PCT/JP03/02500 filed on 3/4/2003.

The preliminary amendment filed on 4/24/2006 amending claims 1, and canceling claims 7-8, and 15 is acknowledged. Claims 1-6 and 9-14 are pending.

Applicant's election without traverse of Group I, claims 1-5 and 13, in the communication filed on 4/24/2006 is acknowledged. Claims 6, 9-12 and 14 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claims 1-5 and 13 are at issue and are present for examination.

#### ***Priority***

Acknowledgement is made of applicants claim for foreign priority of JP 2002-057527 of 3/4/2002 and JP 2002-245994 of 8/26/2002.

#### ***Claim Objections***

Claim 13 is objected to because of the recitation "an enzyme agent" should be "an enzyme". Appropriate correction is required.

Claim 13 is objected to because of the recitation "the polypeptide according to claim 1 or a sulfotransferase which comprises the polypeptide according to claim 1". It is appropriate to recite either the polypeptide according to claim 1 or a sulfotransferase which comprises the polypeptide according to claim 1, and reciting both are unnecessary and redundant. Appropriate correction is required.

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Claims 5 and 13 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 5 and 13 is not further limiting of claim 1.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite and vague for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In the present instance, claim 1 recites in line 4 “and/or transposition)” which is unclear as to the scope of the claims that is encompassed. What is transposition?

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4, 5 and 13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a polypeptide of a sulfotransferase of SEQ ID NO: 2 from human, does not reasonably provide enablement for any or all sulfotransferase or any sulfotransferase having one or more amino acid substitutions, deletions, insertion, addition and/or transposition of at least one amino acid in the amino acid sequence of SEQ ID NO: 2 or any sulfotransferase having 90% or more sequence homology to SEQ ID NO: 2. The

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specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Claims 1 and 5 are so broad as to encompass any or all sulfotransferase or any or all sulfotransferase having one or more amino acid substitutions, deletions, insertion, addition and/or transposition of at least one amino acid in the amino acid sequence of SEQ ID NO: 2 or any sulfotransferase having 90% or more sequence homology to SEQ ID NO: 2. Claim 4 recites that the glycosaminoglycan is heparin or heparan sulfate. Claim 13 recites that the sulfotransferase synthesizes sulfated-glycosaminoglycan by transferring a sulfate group from a sulfate group donor to a glycosaminoglycan, a sulfate group acceptor. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of sulfotransferase broadly encompassed by the claims. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. However, in this case the disclosure is limited to the nucleotide and encoded amino acid sequence of only one sulfotransferase.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims, and the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any

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protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple point mutations or substitutions.

The specification does not support the broad scope of the claims which encompass any or all sulfotransferase or any or all sulfotransferase having one or more amino acid substitutions, deletions, insertion, addition and/or transposition of at least one amino acid in the amino acid sequence of SEQ ID NO: 2 or any sulfotransferase having 90% or more sequence homology to SEQ ID NO: 2 because the specification does not establish: (A) regions of the protein structure which may be modified without effecting sulfotransferase activity; (B) the general tolerance of sulfotransferase to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any or all sulfotransferase residues with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any or all sulfotransferase or any or all sulfotransferase having one or more amino acid substitutions, deletions, insertion, addition and/or transposition of at least one amino acid in the amino acid sequence of SEQ ID NO: 2 or any sulfotransferase having 90% or more sequence homology to SEQ ID NO: 2. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of any or all sulfotransferase having the desired biological characteristics is unpredictable and the experimentation left to those skilled in

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the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-2, 4-5 and 13 are rejected under 35 U.S.C. 102(e) as being anticipated by Liu et al. (WO2004/005475 A2, publication 1/23/2004, claimed priority 60/394,199 of 7/5/2002). Liu et al. disclose a sequence of a human protein, which is 100% identical to SEQ ID NO: 2 (amino acid 1-346) of the instant application. Liu et al. also disclose that the protein is heparan sulfate 3-O-sulfotransferase 5 polypeptide and nucleic acid molecules encoding the same. Xia et al. further disclose that the polypeptide having biological activity in specific heparan sulfate 3-O-sulfotransferase reactions, which provide unique modified heparan sulfate. Therefore, Xia et al. anticipates claims 1-2, 4-5 and 13 of the instant application.

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Claims 1-2, 4-5 and 13 are rejected under 35 U.S.C. 102(a) as being anticipated by Xia et al. (Heparan sulfate 3-O-sulfotransferase isoform 5 generates both an antithrombin-binding site and an entry receptor for herpes simplex virus, type 1, J Biol Chem. 2002 Oct 4; 277(40): 37912-9. Epub 2002 Jul 23, see IDS). Xia et al. disclose a sequence of a human protein, which is 100% identical to SEQ ID NO: 2 (amino acid 1-346) of the instant application. Xia et al. also disclose that the protein is heparan sulfate 3-O-sulfotransferase 5 polypeptide which has biological activity in specific heparan sulfate 3-O-sulfotransferase reactions, which provide unique modified heparan sulfate. Therefore, Xia et al. anticipates claims 1-2, 4-5 and 13 of the instant application.

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

#### *Allowable Subject Matter*

Claim 3 is allowable over prior arts of record but objected to since dependent on rejected claim 1. Claim 3 recites "The polypeptide ----, which consists of the amino acid numbers 37-346 in the amino acid sequence --- SEQ ID NO: 2", which is the part of polypeptide region SEQ ID NO: 2 having sulfotransferase activity lacking transmembrane region (amino acid number 1 to amino acid number 36). The prior art does not identify the boundaries of the catalytic domain as being residue 37 -346 in the amino acid sequence of SEQ ID NO: 2. The prior art does not teach any polypeptide of amino acid numbers 37 to amino acid numbers 346 having sulfotransferase activity, which is the processed form of SEQ ID NO: 2. A standard search did not produce any prior art that suggests or teach the claimed invention of a polypeptide of amino acid numbers 37



to amino acid numbers 346 having sulfotransferase activity. The claimed invention is novel and nonobvious over prior art.

### ***Conclusion***

#### **Status of the claims:**

Claims 1-2, 4-5 and 13 are pending.

Claim 3 is objected.

Claims 1-2, 4-5 and 13 are rejected.

No claim is in condition for allowance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Iqbal Chowdhury whose telephone number is 571-272-8137. The examiner can normally be reached on 9:00-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 703-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Iqbal Chowdhury, PhD, Patent Examiner  
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